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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., **Plaintiff,** **v.** **AJANTA PHARMA LIMITED and AJANTA PHARMA USA INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Ajanta Pharma Limited and Ajanta Pharma USA Inc. (collectively, "Ajanta" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"), 9,549,940 ("the '940

patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and 10,314,790 ("the '790 patent") attached hereto as Exhibits A–J (collectively, "the patents in suit").

THE PARTIES

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

3. Upon information and belief, Defendant Ajanta Pharma Limited ("Ajanta Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at Ajanta House, Charkop, Kandivli West, Mumbai-400 067, Maharashtra, India.

4. According to Defendants' website, "Ajanta Pharma is a specialty pharmaceutical company engaged in development, manufacture and marketing of quality finished dosages in domestic and international markets" with over 7,000 employees operating in more than 30 countries across 4 continents. Ajanta Website, http://www.ajantapharma.com/index.aspx (accessed March 26, 2021).

5. Ajanta Ltd.'s Annual Report 2019-2020 states that it experienced "robust growth of 82% in the market" for FY 2020 in the United States. Ajanta Ltd.'s Annual Report 2019-2020 at 3 and 9, http://www.ajantapharma.com/AdminData/AnnualReports/AnnualReportFY2019-20.pdf (accessed March 26, 2021). Ajanta Ltd.'s Annual Report 2019-2020 further states, "[t]his growth was achieved on the back of 7 new product launches and market share gained by [Ajanta Ltd.] existing products. US has played key role in the resilience [Ajanta Ltd.] displayed amidst adversity." Ajanta Ltd.'s Annual Report 2019-2020 at 9, http://www.ajantapharma.com/AdminData/AnnualReports/AnnualReportFY2019-20.pdf (accessed March 26, 2021). Additionally, Ajanta Ltd.'s Annual Report 2019-2020 indicates the company "[r]eceived approvals for 9 ANDAs which lead to a total of 40 approvals (including 1 tentative approval) . . .

.[and] 12 New ANDAs filled with USFDA." Ajanta Ltd.'s Annual Report 2019-2020 at 39, http://www.ajantapharma.com/AdminData/AnnualReports/AnnualReportFY2019-20.pdf (accessed March 26, 2021).

6. Upon information and belief, Ajanta Ltd. is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its various subsidiaries, including Defendant Ajanta Pharma USA Inc., the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) in concert with and/or through its various subsidiaries, including Defendant Ajanta Pharma USA Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

7. Upon information and belief, Defendant Ajanta Pharma USA Inc. ("Ajanta USA") is a corporation operating and existing under the laws of the State of New Jersey, with its principal place of business at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807. Upon information and belief, Ajanta USA is a wholly-owned subsidiary of Ajanta Ltd. Upon information and belief, Ajanta USA acts at the direction of, under the control of, and for the direct benefit of Ajanta Ltd. and is controlled and/or dominated by Ajanta Ltd.

8. Upon information and belief, Ajanta USA is in the business of, *inter alia*: (i) developing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States, including throughout the State of New Jersey; (ii) in concert with and/or

through its parent, including Defendant Ajanta Ltd. and various subsidiaries, the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) alone or in concert with and/or through its parent, including Defendant Ajanta Ltd. and various subsidiaries, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

9. Upon information and belief, Ajanta Ltd. filed ANDA No. 215663 ("the Ajanta ANDA") with FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of generic topiramate extended-release capsule, containing 25 mg, 50 mg, 100 mg, and 200 mg of topiramate ("the Ajanta Products").

10. Upon information and belief, Ajanta Ltd. and Ajanta USA collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products (e.g., Risperidone Tablet (0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg); Clomipramine Hydrochloride Capsules (25 mg, 50 mg, and 75 mg), and Aripiprazole Tablet (2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg), and Tadalafil Tablet (2.5 mg, 5 mg, 10 mg, 20 mg)) that will be manufactured and sold pursuant to an ANDA, throughout the United States, including throughout the State of New Jersey.

11. Upon information and belief, Defendants and/or their affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which Ajanta Ltd. is the named ANDA applicant. Upon information and belief, Defendants each, directly or indirectly, derive substantial revenue from the sales of such generic pharmaceutical products.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1) and N.J. Ct. R. 4:4-4; and/or (ii) Fed. R. Civ. P. 4(k)(2).

14. Upon information and belief, Defendants have purposefully availed themselves of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New Jersey. For example, upon information and belief, Defendants state on their website that they are "gradually building a meaningful presence in the US market with select product portfolio, which include complex technology products to get the competitive advantage in the market place. We expect US market to be our key growth driver in the coming years." Ajanta Website, http://www.ajantapharma.com/overview.html (accessed March 26, 2021). Defendants further state on their website "[o]ur products are already available on the shelf in US through our subsidiary, located in New Jersey, the hub of pharma industry in USA." Ajanta Website, http://www.ajantapharma.com/generics.html (accessed March 26, 2021). In addition, Defendants' website indicates that as of February 2021, Defendants had 42 products approved by FDA with 18 additional products submitted and under approval with FDA. Ajanta Website, http://www.ajantapharma.com/AdminData/InvesterPresentation/InvestorPresentation ofQ3FY2021.pdf (accessed March 26, 2021).

15. This Court has personal jurisdiction over Ajanta USA at least because, upon information and belief: (i) Ajanta USA maintains a principal place of business in New Jersey located at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807; (ii) Ajanta USA is doing business in New Jersey and maintains continuous and systematic

contacts with this Judicial District; (iii) Ajanta USA, together with its parent Ajanta Ltd., is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Ajanta USA, together with its parent Ajanta Ltd., has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (v) Ajanta USA has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.[1]

16. Upon information and belief, Ajanta USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0400533904. Upon information and belief, Ajanta USA is registered with the State of New Jersey's Department of Health as a drug & medical device "manufacturer and wholesaler" and "wholesaler" with Registration Number 5004507. Ajanta USA has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

17. According to Defendants' website, Ajanta USA is based in Bridgewater, New Jersey, and is a wholly-owned subsidiary of Ajanta Ltd. The website further states "[s]ince making the strategic decision to enter the US market, our Research and Development (R&D) team began developing a product portfolio of [ANDA] filings with a mix of Immediate-Release,

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[1] This Court also has personal jurisdiction over Defendants because Ajanta Ltd. and Ajanta USA have previously submitted to the jurisdiction of this Court and have previously availed themselves of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Horizon Medicines LLC, et al v. Ajanta Pharma Ltd., et al.*, Civil Action No. 19-18555 (BRM)(JAD) (D.N.J.) (Ajanta Ltd. and Ajanta USA filed a counterclaim and did not contest jurisdiction.) and *Otsuka Pharmaceutical Co., Ltd. v. Ajanta Pharma Ltd., et al.*, Civil Action No. 14-05876 (JBS)(KMW) (D.N.J.) (Ajanta Ltd. and Ajanta USA filed a counterclaim and did not contest jurisdiction.).

Extended-Release, Delayed-Release, Orally Disintegrating Tablets and Powders." http://www.ajantapharmausa.com/overview.html (accessed March 26, 2021).

18. This Court has personal jurisdiction over Ajanta Ltd. at least because, upon information and belief: (i) Ajanta Ltd. has purposefully directed its activities and the activities of Ajanta USA at residents and corporate entities within the State of New Jersey; (ii) the claims set forth herein against Ajanta Ltd. arise out of or relate to those activities; (iii) Ajanta Ltd.'s contacts with the State of New Jersey (direct and indirect) are continuous and systematic; and (iv) it is reasonable and fair for this Court to exercise personal jurisdiction over Ajanta Ltd.

19. Upon information and belief, Ajanta Ltd.'s tortious acts of (i) preparing and filing ANDA No. 215663 with a paragraph IV certification to the patents in suit for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products before the expiration of the patents in suit; and (ii) directing notice of its ANDA submission to Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of the Ajanta Products by Defendants before the expiration of the patents in suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Ajanta Ltd. and Ajanta USA should reasonably anticipate being sued in New Jersey.

20. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if ANDA No. 215663 is approved, the Ajanta Products will be marketed and distributed by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed

by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Specifically, upon information and belief, Ajanta USA employs a salesforce that includes personnel who regularly and continuously work in this Judicial District[2] and, if Ajanta Ltd. succeeds in obtaining FDA approval, Ajanta USA will use its salesforce to sell the Ajanta Products in the State of New Jersey.

21. Venue is proper for Ajanta USA under 28 U.S.C. §§ 1391 and/or 1400(b), because, *inter alia* Ajanta USA is subject to personal jurisdiction in this Judicial District, as set forth above, has committed and/or will commit further acts of infringement in this Judicial District, as set forth above, and/or does business in this Judicial District through a permanent and continuous presence in the State of New Jersey, as set forth above.

22. Venue is proper for Ajanta Ltd. under 28 U.S.C. §§ 1391 and/or 1400(b) because, *inter alia*, Ajanta Ltd. is subject to personal jurisdiction in this Judicial District, as set forth above, has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth above, and/or continuously transacts business in this Judicial District, as set forth above.

23. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b), 1391(c), and § 1400(b).

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[2] Defendants' website states that its "journey into the US marketplace" includes "a dedicated front end sales and marketing team." Ajanta USA Website, http://www.ajantapharmausa.com/business-development.html (accessed March 26, 2021).

FACTS AS TO ALL COUNTS

24. Supernus's Trokendi XR® is sold and marketed under New Drug Application ("NDA") No. 201635, which was approved by FDA for the manufacture and sale of topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

25. Trokendi XR® is an antiepileptic drug indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

26. Trokendi XR®'s recommended dosage: (i) for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and in patients 6 to 9 years of age is based on weight; (ii) for adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut Syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and for adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

27. NDA No. 201635 pertains to Trokendi XR® 25 mg, 50 mg, 100 mg, and 200 mg.

28. FDA's publication titled, "Approved Drug Products with Therapeutic Equivalence Evaluations," (commonly known as the "*Orange Book*") lists ten (10) patents, specifically the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents, as

covering Supernus's Trokendi XR®. Pursuant to 21 U.S.C. 355(b)(1) and 355(c)(2), these ten (10) patents were submitted to FDA with or after the approval of NDA No. 201635. These ten (10) patents are listed in the Orange Book as covering Trokendi XR®.

29. The '576 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '576 patent.

30. The '580 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '580 patent.

31. The '683 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on March 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '683 patent.

32. The '248 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '248 patent.

33. The '191 patent, entitled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 18, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '191 patent.

34. The ’989 patent, entitled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on March 31, 2015, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’989 patent.

35. The ’940 patent, entitled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on January 24, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’940 patent.

36. The ’004 patent, entitled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on January 31, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’004 patent.

37. The ’983 patent, entitled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on April 18, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’983 patent.

38. The ’790 patent, entitled, “Sustained-Release Formulations of Topiramate,” was duly and legally issued by the United States Patent and Trademark Office on June 11, 2019, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the ’790 patent.

39. On or about February 10, 2021, Ajanta sent a letter purportedly pursuant to § 505(j)(2)(B)(iv)(II) of the FDCA and 21 C.F.R. §§ 314.94, 314.95 regarding the Ajanta

Products and the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents (the "February 10 Notice Letter") to Supernus at 1550 East Gude Drive, Rockville, Maryland 20850.

40. The February 10 Notice Letter was signed by Dennies Varughese, Esq., Pharm.D., of Sterne, Kessler, Goldstein & Fox P.L.L.C.—counsel for Ajanta—and authorized such counsel to accept service of process for Ajanta Ltd.

41. Upon information and belief, ANDA No. 215663 is based upon Trokendi XR® (topiramate extended-release capsule), 25 mg, 50 mg, 100 mg, and 200 mg., as its reference listed drug.

42. Upon information and belief, the Ajanta Products are topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

43. Upon information and belief, the proposed prescribing information for the Ajanta Products includes a header titled, "Indications and Usage," and states that Ajanta Products are indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

44. Upon information and belief, the proposed prescribing information for the Ajanta Products includes a header titled, "Dosage and Administration," and states that: (i) the recommended dose for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and dosing in patients 6 to 9 years of age is based on weight; (ii) the recommended total daily dose as adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut Syndrome is 200 mg to 400 mg orally once daily and with primary generalized

tonic-clonic seizures is 400 mg orally once daily, and the recommended total daily dose as adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) the recommended total daily dose as treatment for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

45. Upon information and belief, the proposed prescribing information for the Ajanta Products will also state under the header "Dosage and Administration" that the Ajanta Products can be taken without regard to meals, to swallow capsule whole and intact, and do not sprinkle on food, chew, or crush.

46. Upon information and belief, the proposed prescribing information for the Ajanta Products includes a header titled, "Description," and states that the Ajanta Products contain the following inactive ingredients: Sugar Spheres, NF Hypromellose (Type 2910), USP Mannitol, USP Docusate Sodium, USP Sodium Benzoate, NF Ethylcellulose, NF Oleic Acid, NF Medium Chain Triglycerides, NF Polyethylene Glycol, NF Polyvinyl Alcohol, USP Titanium Dioxide, USP Talc, USP Lecithin, NF Xanthan Gum, NF Glycerin, USP-NF.

47. Upon information and belief, Ajanta Ltd. and Ajanta USA acted in concert to develop the Ajanta Products and to seek approval from FDA to sell the Ajanta Products throughout the United States, including within this Judicial District.

48. Upon information and belief, both Ajanta Ltd. and Ajanta USA participated in the preparation and/or filing of ANDA No. 215663.

49. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of

the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

50. Upon information and belief, as of the date of the February 10 Notice Letter, Ajanta Ltd. and Ajanta USA were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

51. The February 10 Notice Letter does not include any non-infringement contentions unique to claims 2-18 and 20-30 of the '576 patent, claims 2-16 and 18-31 of the '580 patent, claims 2-24 of the '683 patent, claims 2-13 and 15-20 of the '248 patent, claims 2-24 of the '191 patent, claims 2-13, 16-17, and 19-20 of the '989 patent, claims 2-13, 16-17, and 19-20 of the '940 patent, claims 2-12, 15-16, and 18-30 of the '983 patent, claims 2-11 and 13-15 of the '004 patent, and claims 2-11 and 13-25 of the '790 patent.

52. The February 10 Notice Letter does not include any invalidity contentions to any claim of the '576, '580, '683, '191, '004, and '790 patents. Further, the February 10 Notice Letter does not include any invalidity contentions to claims 1-13 and 15-17 of the '248 patent, claims 1-13 and 15-17 of the '989 patent, claims 1-13 and 15-17 of the '940 patent, claims 1-12, 14-16, and 21 of the '983 patent.

53. Supernus and Defendants did not reach agreement on mutually acceptable terms for an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). As of the filing of this Complaint, Defendants have not produced the Ajanta ANDA to Supernus.

FIRST COUNT
(Defendants' Infringement of the '576 Patent)

54. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

55. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '576 patent is an act of infringement of the '576 patent by Ajanta Ltd. of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

56. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

57. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '576 patent under 35 U.S.C. § 271.

58. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '576 patent under 35 U.S.C. § 271.

59. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '576 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

60. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '576 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

61. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Defendants' Infringement of the '580 Patent)

62. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

63. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '580 patent is an act of infringement of the '580 patent by Ajanta Ltd. of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

64. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

65. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into

the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '580 patent under 35 U.S.C. § 271.

66. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

67. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '580 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

68. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '580 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

69. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

THIRD COUNT
(Defendants' Infringement of the '683 Patent)

70. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

71. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the

Ajanta Products before the expiration of the '683 patent is an act of infringement of the '683 patent by Ajanta Ltd. of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

72. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

73. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '683 patent under 35 U.S.C. § 271.

74. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

75. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '683 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

76. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '683 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

77. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

FOURTH COUNT
(Defendants' Infringement of the '248 Patent)

78. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

79. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '248 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '248 patent is an act of infringement of the '248 patent by Ajanta Ltd. of one or more claims of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

80. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

81. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '248 patent under 35 U.S.C. § 271.

82. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '248 patent under 35 U.S.C. § 271.

83. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '248 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

84. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '248 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

85. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

FIFTH COUNT
(Defendants' Infringement of the '191 Patent)

86. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

87. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '191 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '191 patent is an act of infringement of the '191 patent by Ajanta Ltd. of one or more claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A).

88. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

89. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '191 patent under 35 U.S.C. § 271.

90. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will

induce and/or contribute to third-party infringement of one or more claims of the '191 patent under 35 U.S.C. § 271.

91. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '191 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

92. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '191 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

93. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

SIXTH COUNT
(Defendants' Infringement of the '989 Patent)

94. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

95. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '989 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '989 patent is an act of infringement of the '989 patent by Ajanta Ltd. of one or more claims of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

96. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

97. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '989 patent under 35 U.S.C. § 271.

98. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '989 patent under 35 U.S.C. § 271.

99. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '989 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

100. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '989 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

101. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

SEVENTH COUNT
(Defendants' Infringement of the '940 Patent)

102. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

103. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '940 patent to obtain approval to engage in the

commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '940 patent is an act of infringement of the '940 patent by Ajanta Ltd. of one or more claims of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

104. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

105. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '940 patent under 35 U.S.C. § 271.

106. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '940 patent under 35 U.S.C. § 271.

107. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '940 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

108. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '940 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

109. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

EIGHTH COUNT
(Defendants' Infringement of the '004 Patent)

110. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

111. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '004 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '004 patent is an act of infringement of the '004 patent by Ajanta Ltd. of one or more claims of the '004 patent under 35 U.S.C. § 271(e)(2)(A).

112. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

113. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '004 patent under 35 U.S.C. § 271.

114. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '004 patent under 35 U.S.C. § 271.

115. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '004 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

116. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '004 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

117. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

NINTH COUNT
(Defendants' Infringement of the '983 Patent)

118. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

119. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '983 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the Ajanta Products before the expiration of the '983 patent is an act of infringement of the '983 patent by Ajanta Ltd. of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(A).

120. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

121. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into

the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '983 patent under 35 U.S.C. § 271.

122. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '983 patent under 35 U.S.C. § 271.

123. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '983 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

124. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '983 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

125. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

TENTH COUNT
(Defendants' Infringement of the '790 Patent)

126. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

127. Upon information and belief, Ajanta Ltd. submission and filing of ANDA No. 215663 with a paragraph IV certification to the '790 patent to obtain approval to engage in the commercial manufacture, use, and/or sale in, and/or importation into, the United States of the

Ajanta Products before the expiration of the '790 patent is an act of infringement of the '790 patent by Ajanta Ltd. of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2)(A).

128. Upon information and belief, Ajanta Ltd. and Ajanta USA will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the Ajanta Products upon, or in anticipation of, FDA approval of ANDA No. 215663.

129. Upon information and belief, Ajanta Ltd. and Ajanta USA's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products will infringe, directly and/or indirectly, one or more claims of the '790 patent under 35 U.S.C. § 271.

130. Upon information and belief, the commercial offering for sale and/or sale of the Ajanta Products by Ajanta USA, purportedly at the direction and control of Ajanta Ltd., will induce and/or contribute to third-party infringement of one or more claims of the '790 patent under 35 U.S.C. § 271.

131. Upon information and belief, the factual and legal bases in the February 10 Notice Letter regarding the '790 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

132. Defendants acted without a reasonable basis for believing that they would not be liable for infringement of the '790 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

133. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless Ajanta Ltd. and Ajanta USA are preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Supernus respectfully requests the following relief:

i. A Judgment declaring that the patents in suit are valid and enforceable;

ii. A Judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that the submission to FDA and filing of ANDA No. 215663 with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the Ajanta Products was an act of infringement of the patents in suit by Defendants;

iii. A Judgment pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the Ajanta Products before the expiration of the patents in suit (including any regulatory extensions) would directly and/or indirectly infringe the patents in suit;

iv. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, that the effective date of any approval of the Ajanta Products shall be no earlier than the date on which the patents in suit expire (including any regulatory extensions);

v. An Order, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and any person in active concert or participation or privity with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation in the United States of the Ajanta Products until the expiration of the patents in suit (including any regulatory extensions);

vi. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, awarding Supernus damages or other monetary relief if Defendants commercially manufacture, use, offer to

sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 215663 that infringes the patents in suit;

vii. A Judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, declaring that Defendants' infringement of the patents in suit is willful and awarding Supernus enhanced damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 215663 that infringes the patents in suit (including any regulatory extensions);

viii. A Judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Supernus its attorneys' fees and costs; and

ix. Such other and further relief as this Court may deem just and proper.

Dated: March 26, 2021

By: s/ William C. Baton

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: March 26, 2021

By: s/ William C. Baton
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